17

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
EWOLDT, GERALD R	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 03/31/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/382,088	HOPE ET AL.	
	Examiner	Art Unit	
	G. R. Ewoldt, Ph.D.	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 October 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *51 and 60-78* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *51 and 60-78* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. A request for continued examination (RCE) under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's amendment and remarks filed 10/31/03 have been entered.

2. Claim 51 and newly added Claims 60-78 are under examination.

3. The black and white copies of the drawings submitted 10/31/03 have been found to be acceptable. It is unclear to the Examiner whether or not Applicant has also submitted color drawings. If color drawings have been submitted, a proper petition and fee is also required.

4. The declaration filed 5/14/03 has been found to be acceptable.

5. Claims 51 and 60-78 are objected to because of the following informalities:

A) The claims comprise incomplete sentences. Applicant is advised that the claims page should begin with "WE CLAIM" or "WHAT IS CLAIMED IS" (as originally presented), rather than "IN TH [sic] CLAIMS" such that when combined with the claims the combination comprises what can be considered a sentence, e.g., "we claim a method..." rather than "in th claims a method...".

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 60-78 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, for the reasons of record first set forth in the paper mailed 7/17/01 and reiterated in the paper mailed 10/02/02.

Applicant's arguments, filed 10/31/03, have been fully considered but they are not persuasive. Applicant argues, "The specification provides other enabling embodiments, for example but not limited to, the fusion protein of human Hsp47 with N-terminally tagged glutathione-s-transferase (Gst), Hsp47 with leader sequences added on (SEQ ID NOS:19-20), and truncated forms of Hsp47."

Applicant is advised that "the fusion protein of human Hsp47 with N-terminally tagged glutathione-s-transferase" comprises SEQ ID NO:6 and the functional "truncated forms of Hsp47" disclosed in the specification comprise SEQ ID NO:3, i.e, Applicant's examples are the species found enabled.

Applicant argues, substituted versions of the composition are described, for example, on page 7, and the art-recognized conservative amino acid substitutions included in those versions are described in Table 1 on page 9."

Applicant is advised that *none* of the mutated or substituted forms of Hsp47 disclosed in the specification have been shown to function in the method of the instant claims.

Applicant argues "Secondly, Applicants respectfully disagree with the Examiner's argument that the specification does not provide sufficient direction with regard to HSP47 peptides protecting against immune-mediated damage by other immune cells. There is nothing in the literature that contradicts the notion that HSP47 peptides reduce immune mediated damage by cells other than CIK. The specification also provides embodiments demonstrating immunoprotective effect without the administration of CIK cells. For example, the murine bone marrow transplant studies described on page 55 of the specification and in Figure 15."

Applicant is advised that a lack of contradiction in the literature does not in itself comprise sufficient enablement for the method of the instant claims. Regarding "embodiments demonstrating immunoprotective effect without the administration of CIK cells," a lack of CIK cells does not demonstrate that the asserted immunoprotection of the instant claims is generated against any specific cell types such as lymphocytes or NK cells.

8. The following are new grounds of rejection.

9. Claims 70-72 and 74-78 are rejected under 35 U.S.C. § 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed. This is a new matter rejection.

The specification and the claims as originally filed do not provide support for the invention as now claimed, specifically:

A) "a sequence at least 80% identical to SEQ ID NO:6" (Claim 70).

B) "a sequence at least 90% identical to SEQ ID NO:6" (Claim 71).

C) "a sequence at least 95% identical to SEQ ID NO:6" (Claim 72).

D) "a sequence at least 70% identical to SEQ ID NO:3" (Claim 74).

E) "a sequence at least 80% identical to SEQ ID NO:3" (Claim 75).

F) "a sequence at least 90% identical to SEQ ID NO:3" (Claim 76).

G) "a sequence at least 95% identical to SEQ ID NO:3" (Claim 77).

H) "a nucleic acid sequence which hybridizes with a nucleic acid sequence of SEQ ID NO:4" (Claim 78).

Applicant's remarks, filed 10/31/03, indicates that "The newly claimed material is described in the specification and figures as filed with no new matter added by these amendments or claims." It is noted however, that no specific support for the new claims has been cited and none has been found. For example, whereas Claim 70 recites a method employing "a sequence at least 80% identical to SEQ ID NO:6", the specification discloses this 80% identity limitation only in the context of a polynucleotide. Applicant's mixing and matching of limitations is not supported by the specification and comprises the introduction of new matter into the claims. Regarding "a nucleic acid sequence which hybridizes with a nucleic acid sequence of SEQ ID NO:4", the specification discloses only hybridizing under "stringent" or "moderately stringent" conditions, and also fails to disclose hybridization specifically with a nucleic acid sequence of SEQ ID NO:4.

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claim 60 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, "an Hsp47-related polypeptide" has been defined in the specification as "any polypeptide which has immunoprotecting properties which are similar to that of Hsp47 polypeptide as defined herein. For example, human Hsp47 polypeptide has been shown to protect endothelial cells from lysis from CIK cells. An Hsp47-related immunoprotective polypeptide would be one which shares either qualitatively or quantitatively this or other immunoprotective properties of human Hsp47." This vague and indefinite definition places so few limitations on the "Hsp47-related polypeptide" of the claim that the metes and bounds of the claim cannot be known.

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claims 51 and 60-78 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Hoppe et al. (1955, IDS).

Hoppe et al. teaches a method for reducing immune-mediated damage to cells, tissues or organs comprising contacting a cell, tissue or organ with an immunoprotective amount of polypeptide comprising Hsp47 which comprises the amino acid sequence AVLSAEQLR (SEQ ID NO:3), or SEQ ID NO:6, which encompasses the claimed variants thereof and a sequence which hybridizes with a nucleic acid sequence of SEQ ID NO:4, wherein the immune-mediated damage is caused by CIK cells (see particularly the last line of the abstract).

The reference clearly anticipates the claimed invention.

14. No claim is allowed.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (571) 272-0843. The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. **Please Note**: inquiries of a general nature or relating to the status of this application should not be directed to the Examiner but rather should be directed to the Technology Center 1600 Customer Service Center at (703) 308-0198.

G.R. Ewoldt, Ph.D.
Primary Examiner
Technology Center 1600

1/14/04
G.R. EWOLDT, PH.D.
PRIMARY EXAMINER